(b) whether Government have defined the expression 'Mental Asylum' giving it a wider connotation and bringing all types of mental asylums mushrooming all over the country; and

(c) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR) : (a) In pursuance of the Orders of Hon'ble Supreme Court dated 15.10.2001, Committees have been constituted to visit all registered mental hospitals and to submit a report about the state of facilities available for treating the mentally ill people in such registered mental health care centers.

(b) No, Sir.

(c) Does not arise.

Guidelines for approval of Bio-equivalence Centre

2156. MISS MABEL REBELLO: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that there are no guidelines for approval of bio-equivalence centres;

(b) if so, how the approvals are being granted by the Drug Controller; and

(c) whether the Drug Controller-General of India is accepting study reports from Centres which have no approval and when do they propose to come out with guidelines?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR) : (a) to (c) Bio availability is the process by which the drug is released from the oral dosage form and moves to the site of action. Bioavailability data provides an estimate of the fraction of the drug absorbed as well as its subsequent distribution and elimination.

Under the provisions of the Drug and Cosmetics Rules, there is no specific statutory requirement for approval of centres/laboratories which undertake bio-availability or bioeqvalence studies. However, there are internationally accepted norms about the facilities which are required to undertake such studies, the

protocols required to be followed and the manner in which studies need to be conducted including the ethical norms.

Since data on bioavailability/bioequivalence is required to be furnished along with application for approval of New Drugs as per Schedule Y of the Drugs and Cosmetics Rules, the facilities and expertise available with such centres/ laboratories is now being ascertained through experts, and on satisfactory reports, such centres are being approved for the purpose of acceptance of bioequivalence studies conducted by them.

Normally, bioavailability studies are being conducted by the departments of pharmacology in major medical institutions, some pharmacy colleges, in-house R&D centres of few pharma industry and private research laboratories.

Guidelines about the infrastructural requirements and working norms for bioequivalence studies are under preparation for consideration of the Drug Technical Advisory Board (DTAB). Steps are also being taken to assess the laboratories/centres which have been conducting these studies since earlier period.

Treatment and rehabilitation of HIV infected children

†2157. SHRI DEVI PRASAD SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the information given in a press conference on 1st November, 2001 by Delhi Branch of Indian Academy of Paediatrics, in which it has been stated (that about two hundred children get infected by HIV in the country everyday, whereas more than eleven thousand children die due to this disease-every year; and

(b) if so, the details of efforts being made by Government for the treatment and rehabilitation of such children?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR): (a) Yes, Sir. The estimates stated regarding the number of children infected every day with HIV are exaggerated. The estimated number of HIV infected children born in the country is approximately 30,000 per year with an HIV prevalence rate of 0.3% among pregnant mothers.

† Original notice of the question was received in Hindi.